

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 10, 2018

Jeff Jones Agent for Sanitized (USA) Inc. c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Subject: Label Amendment – Revise Label Product Name: Sanitizes Brand PLA EPA Registration Number: 91742-1 Application Date: June 26, 2018 Decision Number: 542891

Dear Mr. Jones:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Wanda Henson by phone at (703) 308-6345 or via email at <u>henson.wanda@epa.gov</u>

Sincerely,

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Demson Fuller, Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure

SANITIZED^{®*} BRAND PLA

Alternate Brand Names: Sanitized Brand PL 96-40

FOR INDUSTRIAL USE

SANITIZED® is the registered trademark/brandname of Sanitized (USA) Inc. for its BACTERIOSTATIC Chemicals. *This product is not registered for use as a sanitizer.

A BACTERIOSTATIC TREATMENT THAT CONTROLS ODORS, DETERIORATION AND DISCOLORATION OF PLASTICS AND POLYMERS CAUSED BY MICROBIAL GROWTH IN THE PRESENCE OF MOISTURE.

ACTIVE INGREDIENT

KEEP OUT OF REACH OF CHILDREN CAUTION

See side panel for additional precautionary statements

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center of doctor. Do not give anything by mouth to an unconscious person. If inhaled: Move person to fresh air. If person is not breathing, call 911 or ambulance, then

give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Emergency CONTACT (24-Hour-Number), GBK/Infotrac ID 106460: USA domestic 1 800 535 5053 or international (001) 352 323 3500.

> Manufactured by SANITIZED (USA) Inc. 15720 Brixham Hill Ave, Suite 300 Charlotte, NC, 28277 Tel. (704) 926-6570

> > NET WEIGHT:

EPA Reg. No. 91742-1

V: 09/12/18

ACCEPTED EPA Est. No. 91742-CHE-1 10/10/2018 Under the Federal Insecticide, Fungicide

and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 91742-1

SANITIZED[®] BRAND PLA BRAND BACTERIOSTAT

A broad spectrum bacteriostatic, fungistatic and deodorizing agent for controlling odors, deterioration and discoloration of plastics and polymers caused by microbial growth in the prese nce of moisture

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if inhaled or absorbed through skin. Avoid contact with skin, eyes or clothing. Do not breathe dust. When handling for any purpose, use dust/mist filtering respirator (such as MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with an N, P or HE pre-filter. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, In postclet is to be to have be hard to be the total angle entrements containing the product of the takes, attentiation, points, estuartes, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal STORAGE

Store in original containers and place in locked storage area. Keep from freezing. Moisture sensitive. Keep container closed until ready for use and after use. Store below 130°F in an area inaccessible to children PESTICIDE DISPOSAL

Wastes resulting from the use of the product may be disposed of on-site or at an approved waste disposal facility. CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Completely empty liner of clinging particles by shaking and tapping sides and bottom. Empty residue into application equipment. Dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. Triple rinse drum (or equivalent) promptly after emptying. Offer for recycling if available or place in trash.

SPILL OR LEAK PROCEDURES

Minor spills, shovel into an approved disposal container and, vacuum contaminated areas. Avoid creating dusty conditions. Take special care to avoid contamination of equipment and facilities during clean up procedures and waste disposal.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

- For processing or manufacturing use. Additive for Plastics and Polymers.
 - Do not use in the manufacture or treatment of items that may come in contact with food. Use only under an agreement with Sanitized (USA) Inc, Charlotte, NC.

 - Not for diaper laundry application or for use in products to be used in or on heating, ventilation, air conditioning (HVAC) coils, textile application, or agricultural plastic/ Polymer films and/ or mulches.
 - Do not use for the production of health care products or products intended to decrease the transmission of disease (items regulated by the Food & Drug Administration). Finished products incorporating the above product may not make claims of antimicrobial activity that exceed
 - what is permitted in PR Notice 2000-1.

PLASTICS/ POLYMERS

Incorporate 0.1% - 0.5% PLA, as received, based upon the total weight of the plastic/polymer mix. Insure that the PLA is evenly & thoroughly dispersed throughout the mix. Deposit 0.1% - 0.35% PLA on the polymer by mixing in a liquid carrier. For ease of handling & to reduce the possibilities of dusting, concentrates containing PLA can be prepared by compounding with pelletized resins and/or preparing dispersions of liquid materials. The pellets are placed in a mixing drum and tumbled together with processing aids such as mineral oil to insure an even coating over the surface of the pellet. Resin concentrates can be prepared containing 10% PLA & 90% resin. Concentrates are then mixed with virgin resins resulting in 0.1% - 0.5% PLA based upon the total weight of the resin mixture.

For specific end use sites, see attached technical bulletin.

TECHNICAL BULLETIN DESCRIPTION OF ACCEPTED USE SITES SANITIZED BRAND PLA EPA REG. NO. 91742-1

Sanitized Brand PLA can be incorporated, following the directions on the product label, in the following items for their protection against noxious bacteria/microorganism causing odors, stains or premature deterioration of the item.

INDUSTRIAL USES/BUILDING MATERIALS

Conveyor belts, counter and table tops, fire hoses, floor waxes & sealers, flooring (concrete, plastic, coatings), insulating material, Portland cement (concrete, mortar, grout and reinforcements), silage wraps, earplugs

HOME FURNISHING/JANITORIAL

Cutting boards (synthetic), exercise equipment, garbage bags, garbage cans & liners, brushes & brooms, mops & mop buckets, sponges, toilets & urinals, storage containers, bath accessories (floor mats & shower curtains)

PERSONAL ITEMS

Hair brushes, combs, toothbrushes (bristles & handles), cards & licenses (playing cards, credit cards, driver's license), currency, non-woven shoes & shoe innersoles & linings, non-woven products

Important Notice: No pesticidal claims for an item containing Sanitized Brand PLA can be made, such as "antimicrobial cutting board" or "bacterial sponge". However, the treated item can be marketed stating that it contains an antimicrobial chemical which prevents the formation of odor causing or stain producing microorganisms, or bacteria which lead to the premature deterioration of the article (e.g. rotting).

Date: 09/12/18